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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/935,717	09/23/1997	MICHAEL CATT	IMIN.P-014	8965

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OPPEDAHL AND LARSON LLP
P O BOX 5068
DILLON, CO 80435-5068

EXAMINER

PORTNER, VIRGINIA ALLEN

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 01/02/2003

22

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/935,717

Applicant(s)

Catt

Examiner

Portner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Oct 15, 2002
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-30 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-30 is/are rejected.
- 7) ☒ Claim(s) 17, 18, 23, 24, and 28-30 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

Claims 1 and 5-10 have been canceled.

New claims 11-30 have been submitted and are under consideration.

Rejections Maintained

1. Claims 11-16, 19-22, 25-27 are rejected as previously applied to claims 1, 5-10 under 35 U.S.C. 102(b) as being anticipated by Catt et al WO 95/13531 for reasons of record in papers 2,8 and 11.

Allowable Subject Matter

2. Claims 17-18, 23-24, and 28-30 are objected to as being dependent upon a rejected base claim, and some of the claims are rejected under 35 U.S.C. 112, second paragraph below, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims, and amended to overcome the rejection under 35 U.S.C. 112, second paragraph.

3. The claims (claims 17-18, 23-24, and 28-30) contain allowable subject matter as the applied prior art does not teach, nor reasonably suggest the lip portion, designated 127, shown in figures 1 and 9 of the instant specification.

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Response to Arguments

4. Applicant's arguments filed October 10, 2002 have been fully considered but they are not persuasive.

5. The rejection of claims 11-16, 19-22, 25-27 under 35 U.S.C. 102(b) as being anticipated by Catt et al WO 95/13531 is traversed on the grounds that the instantly claimed invention distinguishes over Catt et al (WO95/13531) by reciting "means for initiation of the reading device engages the assay device in a lock-and-key interaction".

6. It is the position of the examiner that Catt et al discloses the instantly claimed test kit (see Catt et al (WO95/13531, page 6, lines 30-31; page 35, claim 22) of **claim 11**, which comprises (see Catt et al, WO95/13531, page 4, lines 13-14)

a. an assay device having a detection zone (see page 4, lines 16-23); and

b.a reading device (see page 4, lines 31-37 and page 5, lines 5-15), the reading device comprising means for initiation (the actuating means causes initiation of the reading device, see page 5, lines 13-15), wherein the means for initiation of the reading device engages the assay device in a lock-and-key (interlocking means is a lock and key relationship, see page 5, lines 5-10) interaction, whereby the reading device is initiated when the assay device is positioned correctly within the reading device in the lock and key engagement (see page 26, lines 5-7; page 17, lines 7-8; page 18, lines 1-4; page 5, lines 18-28 and page 5, lines 34-37; page 7, lines 4-9 and lines 23-24).

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Only claims 17-18, 23-24, and 28-30 distinguish over the applied prior art as the WO95' reference does not disclose or teach the structural "lip portion" shown as component "127" in figure 1.

Support for anticipation:

Catt et al (WO95/13531) anticipates **claim 12:** "assay device comprises a porous carrier strip disposed with a hollow casing" (see Catt et al, WO95/13531, page 3, lines 30-37 and page 4, lines 1-14) and the detection zone being defined to one in which the assay result is revealed "by specific binding of a detectable material directly or indirectly to a binding agent immobilized in the detection zone(see Catt et al, (WO95/13531, page 3, lines 35-37 and page 4, line 1).

Catt et al (WO95/13531) anticipates **claim 13:** "the means for initiation of said reading device comprises a switch actuator", and said device comprises a contact portion, "said contact portion and said switch actuator engaging in a lock-and-key engagement." (See Catt et al, WO95',page 34, claim 13, lines 29-33; see page 24, lines 27-31). The inter-relationship of the assay device and the reading device is one that is interlocking (see WO95', page 34, claim 12), a lock and key relationship (see WO95', figures 6 and 7).

Catt et al (WO95/13531) anticipates **claim 14:** "the switch actuator comprises a fixed projecting portion and a displaceable projecting portion (see page 24, lines 27-37 (fixed pin) and page 25,

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lines 1-5 (spring mechanism) and page 25, lines 14-17 (bottom 504 of Figure 6, is the initiation actuating means that imitates the determination of optical sensing (page 25, lines 16-17; see Figures 5, 6 and 7).

Catt et al (WO95/13531) anticipates **claim 15**: “the reading device further comprises means for pressing an assay device inserted into the reading device against the switch actuator” (see page 25, lines 3-5 and 7-17).

Catt et al (WO95/13531) anticipates **claim 16**: “ wherein the reading device further comprises a cam that deflects the assay device away from the switch actuator unless the assay device is correctly positioned within the reading device” (see page 19, lines 15-18 “ biasing means” being “one or more spring-loaded plates or pins to further enhance the positive location of the assay device within the slot”). The biasing means would serve to selectively position the assay device so as to prevent insertion that is not the correct positive location.

Catt et al (WO95/13531) anticipates **claim 19**: “ wherein the means for initiation of said reading device comprises a switch actuator, and wherein said assay device comprises a contact portion and the contact portion and the switch actuator engage in a lock-and-key engagement. (See Catt et al, WO95',page 34, claim 13, lines 29-33; see page 24, lines 27-31). The inter-relationship of

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the assay device and the reading device is one that is interlocking (see WO95', page 34, claim 12), a lock and key relationship (see WO95', figures 6 and 7).

Catt et al (WO95/13531) anticipates **claim 20**: the switch actuator comprises a fixed projecting portion and a displaceable projecting portion (see WO95', page 24, lines 27-37 (fixed pin); page 25, lines 1-5 (spring mechanism); page 25, lines 14-17: position 504 of Figure 6), is the initiation actuating means that imitates the determination of optical sensing (page 25, lines 16-17; see Figures 5, 6 and 7).

Catt et al (WO95/13531) anticipates **claim 21**: “the reading device further comprises means for pressing an assay device inserted into the reading device against the switch actuator” (see page 25, lines 3-5 and 7-17).

Catt et al (WO95/13531) anticipates **claim 22**: “wherein the reading device further comprises a cam that deflects the assay device away from the switch actuator unless the assay device is correctly positioned within the reading device” (see page 19, lines 15-18 “biasing means” being “one or more spring-loaded plates or pins to further enhance the positive location of the assay device within the slot”). The biasing means would serve to selectively position the assay device so as to prevent insertion that is not the correct positive location

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Catt et al (WO95/13531) anticipates **claim 25**: the switch actuator comprises a fixed projecting portion and a displaceable projecting portion (see WO95', page 24, lines 27-37 (fixed pin); page 25, lines 1-5 (spring mechanism); page 25, lines 14-17: position 504 of Figure 6, is the initiation actuating means that imitates the determination of optical sensing (page 25, lines 16-17; see Figures 5, 6 and 7 ; see recess and interface portions shown in figures).

Catt et al (WO95/13531) anticipates **claim 26**: “the reading device further comprises means for pressing an assay device inserted into the reading device against the switch actuator” (see page 25, lines 3-5 and 7-17).

Catt et al (WO95/13531) anticipates **claim 27**: “ wherein the reading device further comprises a cam that deflects the assay device away from the switch actuator unless the assay device is correctly positioned within the reading device” (see page 19, lines 15-18 “ biasing means” being “one or more spring-loaded plates or pins to further enhance the positive location of the assay device within the slot”). The biasing means would serve to selectively position the assay device so as to prevent insertion that is not the correct positive location

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New Claims/New Claim Limitations/New Grounds of Rejection

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claim 11 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1,6-9 (specifically the limitations of claim 9, defined through dependence upon claims 1, 6-8) of U.S. Patent No. US Pat. 6,235,241 and claims 1, 5 and 6 of US Patent No. 6,451,619. Although the conflicting claims are not identical, they are not patentably distinct from each other because the allowed claims recite the presence of additional

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reagents, thus defining a species of kit of the now claimed genus of kits of instant claim 11. A species anticipates the now claimed genus of kits. The instantly claimed kit of claim 11 is the equivalent to or the same kit as those allowed. Structurally and functionally the components of the allowed kit claims are included in the instantly claimed kit of claim 11.

Claim Rejections - 35 U.S.C. § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 12-14, 16-30 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: the labeled reagent which specifically binds to the porous carrier in the detection zone. While claim 12 depends from claim 11 which recites the phrase “labeled reagent” thus providing antecedent basis for the phrase recited in claim 12, the labeled reagent is not positively recited in claim 11 so as to be present in the assay device.

The claim limitations set forth in claim 11 requires the assay device to have a detection zone, but the no labeled reagent is required to be immobilized on the surface of the carrier, nor to be present in the device. The functional limitations are recited in claim 11 “wherein the presence of the analyte in the fluid sample is indicated by accumulation of a labeled reagent within the detection zone” define a process step of using the device, but does not define the presence of any

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labeled reagent in or on the assay device. The labeled reagent can be added externally from the device. The functional limitations define the detection zone to be one that is capable of accumulating the labeled reagent. The claim limitations recited in claim 12, directed to the labeled reagent specifically binding the porous carrier in the detection zone are unclear as the nature and type of labeled reagent has not been structurally, biologically or chemically defined to be present in the device, and the molecule in the detection zone that specifically binds to the undefined labeling reagent that is not present in or on the assay device of claim 11, is unclear in light of the labeling reagent not having been defined to be any specific type of reagent. From the claim limitations set forth in claim 12, it appears that the labeling reagent specifically binds the carrier material as no other material has been set forth in the claim(s). The labeling reagent which specifically binds the porous material would not migrate through the porous carrier because it would specifically bind to whatever location to which it is applied. The claimed invention is not clearly or distinctly claimed.

Claims 12-14, 16-30 recite "wherein" clauses. While a "wherein" clause clearly can further limit a prior claim that positively sets forth a component of the claimed invention, a dependent claim that adds an additional component to the prior claim, should recite the phrase -- further comprises-- to positively set forth the invention.

Conclusion

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11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

12.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (703)308-7543. The examiner can normally be reached on Monday through Friday from 7:30 AM to 5:00 PM except for the first Friday of each two week period.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for this group is (703) 308-4242.


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The Group and/or Art Unit location of your application in the PTO will be Group Art Unit 1645. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to this

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vgp

December 16, 2002


LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600